

PTO/SB/21 (08-06)

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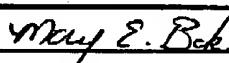
Total Number of Pages In This Submission 4

Application Number	09/806,370	RECEIVED
Filing Date	October 3, 2001	CENTRAL FAX CENTER
First Named Inventor	Holmes et al.	
Art Unit	1645	OCT 23 2006
Examiner Name	V. Portner	
Attorney Docket Number	39,383-00	

ENCLOSURES (Check all that apply)

<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance Communication to TC
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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Howson & Howson LLP		
Signature			
Printed name	Mary E. Bak		
Date	10-23-2006	Reg. No.	31,215

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Typed or printed name Summer Uchlin Date 10-23-2006

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33,383-00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No.	: 09/806,370	Confirmation No.: 8568
Applicant	: Holmes et al.	
Filed	: October 3, 2001	
TC/A.U.	: 1645	
Examiner	: V. Portner	
Customer No.	: 00270	
Title	: MUTANT CHOLERA HOLOTOXIN AS AN ADJUVANT	

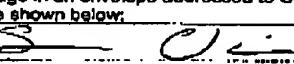
Mail Stop Appeal - Patents
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 Alexandria, VA 22313-1450

AMENDMENT UNDER 37 CFR § 41.33

Sir:

This paper is filed after the Notice of Appeal, but prior to the Appeal Brief, and is to reduce the issues for appeal. Specifically, this paper is filed to cancel subject matter added to the specification by way of the Amendment and Response filed on July 12, 2004. Appellants are requesting deletion of the sequence listing and the phrase "SEQ ID NO: 1" on page 38, lines 7-34. These specification amendments moot the outstanding new matter rejection under 35 USC § 132(a). These amendments were not presented earlier since the Declaration, which at that time of filing, was believed to be fully compliant, but was not entered by the Examiner for assertedly being defective.

Amendments to the Specification begin on page 2.

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AMENDMENTS TO THE SPECIFICATION

Amend the paragraph on page 38, lines 7-34, according to the following:

The antigenic compositions of this invention also comprise CT-CRM containing at least one additional mutation at a position other than at amino acid residue 29. International application WO 93/13202 (36), which is hereby incorporated by reference, describes a series of mutations in the A subunit which serve to reduce the toxicity of the cholera holotoxin. These mutations include making substitutions for the arginine at amino acid 7, the aspartic acid at position 9, the arginine at position 11, the histidine at position 44, the valine at position 53, the arginine at position 54, the serine at position 61, the serine at position 63, the histidine at position 70, the valine at position 97, the tyrosine at position 104, the proline at position 106, the histidine at position 107, the glutamic acid at position 110, the glutamic acid at position 112, the serine at position 114, the tryptophan at position 127, the arginine at position 146 and the arginine at position 192. The nucleotide sequence encoding the A subunit of the cholera holotoxin is set forth in International application WO 93/13202 (SEQ ID NO: 1). International application WO 98/42375 (37) which is hereby incorporated by reference, describes making a substitution for the serine at amino acid 109 in the A subunit, which serves to reduce the toxicity of the cholera holotoxin. Therefore, using conventional techniques, mutations at one or more of these additional positions are generated.

Please delete the two (2) page sequence listing.

33.383-00

The Director is hereby authorized to charge any deficiency in any fees due with the filing of this paper or during the pendency of this application, or credit any overpayment in any fees to our Deposit Account No. 08-3040.

Respectfully submitted,

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